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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,639

11/15/2005

Daniel Yachia

26753U

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12/23/2008

THE NATH LAW GROUP

112 South West Street

Alexandria, VA 22314

EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,639	Applicant(s) YACHIA ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Microchips, Inc. (WO 02/30401) in view of Uhland et al. (US Patent No. 7,455,667). Microchips discloses the device substantially as claimed including a medical device (Fig. 2) for controlled release of one or more substances (abstract) into a body cavity (page 7, lines 1-5 disclose that the device may be implanted in a patient in a electrically conducting fluid such as urine which would be found in a body cavity) containing an electrolytic fluid (page 6, last line through page 7, line 5 discloses that the device is implanted/inserted into electroconductive/electrolytic fluid of a patient, and one of those bodily fluids is urine) comprising: a power supply having first and second terminals (Fig.

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2); a plurality of blister-like vesicles mounted on a first surface (Fig. 2, 62 and 60 are labeled to identify both the electrodes and the caps, therefore as they are shown to protrude from the surface of the microchip device 52 (which as seen in Fig. 2 discloses that 58 lies on top of the surface of the microchip device and cap 60 lies on top of 58 and together, these form a protrusion which can be considered a "blister-like" vesicle), they can be considered "blister-like" vesicles) mounted on a first surface, each vesicle having at least a metallic portion formed from a first metal (page 5, line 24 through page 6, line 30 discloses that each of the blister-like vesicles are electrodes and both can be made from metal); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection allowing the metallic portion to function as an anode (page 7, line 29 through page 8, line 1 disclose that 60 is the anode and 62 is the cathode, also see page 5, line 24 through page 6, line 30 as well as Fig. 2); and a cathode (62) formed from a second metal attached to the second terminal of the power supply (Fig. 2); wherein the cathode is separated from the anode by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Fig. 2 discloses that there is space between 60 and 62 and that both are exposed to the electrolytic body fluid as the fluid is labeled as 30, see page 7, line 22). Microchips, however, does not disclose that each vesicle is electrically coupled to a switch. Uhland, however, discloses a similar device and further discloses that each vesicle may be connected to a transistor/switch so that each blister could be activated independently of other blisters to selectively control what is exposed/released (col. 15, lines 64 through col. 16, line 6). Therefore it would have been obvious to one

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of ordinary skill in the art at the time of the invention to have modified Microchips with the switches, as taught by Uhland, in order to provide selective release of individual components into the body and provide further and finer control of the device.

In reference to claims 2-4 see page 8, line 34 of Microchips and Fig. 2 and col. 15, lines 64 through col. 16, line 6 of Uhland. In reference to claim 4, Uhland discloses using a remote control device to control the device (col. 9, lines 51-67)

In reference to claim 5, page 7, lines 1-5 disclose that the device may be implanted in vivo in gastrointestinal fluids or urine, which would indicate that the device would be placed in either a digestive tract organ or the urinary bladder.

In reference to claim 6, see page 5, line 29 through page 6, line 1 as well as page 6, lines 24-25.

In reference to claims 12-14, see page 3, lines 33-34.

In reference to claims 15 and 16, see page 8, line 15 through page 9, line 5 of Microchips and col. 9, lines 51-67 of Uhland disclose that the device can be controlled by a microprocessor.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Microchips, Inc. (WO 02/30401) in view of Uhland et al. (US Patent No. 7,455,667) and further in view of Yachia et al. (US Patent No. 6,293,923). Microchips discloses the device substantially as claimed including that the device is used in bodily fluids such as urine to treat the bladder (page 7, lines 1-5), Microchips, however, does not disclose an

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inflatable balloon with magnetic portion and valve. Yachia, however, discloses an inflatable balloon (Fig. 5b, balloon is 1) with magnetic portion (Fig. 13, 3) and a self-sealing valve (Figs. 2, 3a and 3b where valve is 5) for the purpose of delivering a treating device into the bladder so that the device may release drugs to treat the bladder (col. 4, lines 46-48). Yachia further discloses that the device after inflation of the balloon either floats or sinks in the electrolytic fluid (col. 5, lines 64- 65). Yachia further discloses that the applicator is fitted at an end thereof with a gripping device for releasably gripping the device (Fig. 5b, 23). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have coupled Microchips in view of Uhland with the delivery device as taught by Yachia, as the device of Microchips is used for treating the urine/bladder and is implanted within that space, and Yachia discloses a device which delivers a treatment device to the bladder, the device including the balloon and its magnetic and valve elements in order to provide a device which can be delivered to the treatment area and positioned properly to allow for the most effective treatment possible (abstract of Yachia).

Claims 17 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Microchips, Inc. (WO 02/30401) in view of Uhland et al. (US Patent No. 7,455,667) and further in view of Yachia et al. (US Patent No. 6,293,923). Microchips discloses the device substantially as claimed including a system for treating a body cavity of an individual, the system comprising: a medical device (Fig. 2) for controlled release of one

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or more substances (abstract) into a body cavity (page 7, lines 1-5 disclose that the device may be implanted in a patient in a electrically conducting fluid such as urine which would be found in a body cavity) containing an electrolytic fluid (page 6, last line through page 7, line 5 discloses that the device is implanted/inserted into electroconductive/electrolytic fluid of a patient, and one of those bodily fluids is urine) comprising: a power supply having first and second terminals (Fig. 2); a plurality of blister-like vesicles mounted on a first surface (Fig. 2, 62 and 60 are labeled to identify both the electrodes and the caps, therefore as they are shown to protrude from the surface of the microchip device 52 (which as seen in Fig. 2 discloses that 58 lies on top of the surface of the microchip device and cap 60 lies on top of 58 and together, these form a protrusion which can be considered a "blister-like" vesicle), they can be considered "blister-like" vesicles) mounted on a first surface, each vesicle having at least a metallic portion formed from a first metal (page 5, line 24 through page 6, line 30 discloses that each of the blister-like vesicles are electrodes and both can be made from metal); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including allowing the metallic portion to function as an anode (page 7, line 29 through page 8, line 1 disclose that 60 is the anode and 62 is the cathode, also see page 5, line 24 through page 6, line 30 as well as Fig. 2); and a cathode (62) formed from a second metal attached to the second terminal of the power supply (Fig. 2); wherein the cathode is separated from the anode by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Fig. 2 discloses that there is space between 60 and 62 and

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that both are exposed to the electrolytic body fluid as the fluid is labeled as 30, see page 7, line 22). Microchips, however, does not disclose that each vesicle is electrically coupled to a switch. Uhland, however, discloses a similar device and further discloses that each vesicle may be connected to a transistor/switch so that each blister could be activated independently of other blisters to selectively control what is exposed/released (col. 15, lines 64 through col. 16, line 6). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Microchips with the switches, as taught by Uhland, in order to provide selective release of individual components into the body and provide further and finer control of the device.

Microchips in view of Uhland, however, does not disclose an inflatable balloon with magnetic portion and valve. Yachia, however, discloses an inflatable balloon (Fig. 5b, balloon is 1) with magnetic portion (Fig. 13, 3) and a self-sealing valve (Figs. 2, 3a and 3b where valve is 5) for the purpose of delivering a treating device into the bladder so that the device may release drugs to treat the bladder (col. 4, lines 46-48). Yachia further discloses that the device after inflation of the balloon either floats or sinks in the electrolytic fluid (col. 5, lines 64-65). Yachia further discloses that the applicator is fitted at an end thereof with a gripping device for releasably gripping the device (Fig. 5b, 23). Yachia also discloses an inflating device for inflating the balloon (Fig. 4a, 7). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have coupled Microchips with the delivery device as taught by Yachia, as the device of Microchips is used for treating the urine/bladder and is implanted within that space, and Yachia discloses a device which delivers a treatment device to the bladder, the device

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including the balloon and its magnetic and valve elements in order to provide a device which can be delivered to the treatment area and positioned properly to allow for the most effective treatment possible (abstract of Yachia).

In reference to claim 19, Yachia discloses a magnetic displacing member (Fig. 13, 51 and 52) for displacing the device within the body cavity. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Microchips with the magnetic displacing member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 4, lines 62-65).

In reference to claims 20 and 21, Yachia discloses an immobilizing member (Fig. 14, 75) comprising a magnetic portion (72), said immobilizing member being secured onto the individual's body for immobilizing the device at a desired location in the body cavity (Fig. 14). Yachia further discloses that the immobilizing member is a hygienic pad configured to be placed in a garment of the individual (col. 7, lines 39-41). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Microchips with the magnetic immobilizing member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 5, lines 2- 3).

In reference to claims 22-24, Yachia, however, discloses that the gripping device has flanges (Fig. 5a, 23), is magnetic (Fig. 11, 29) and the inflating device comprises an injector (Figs. 4a and 4b, 7). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Microchips with the magnetic

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gripping member and inflating member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 6, lines 56-61).

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Microchips, Inc. (WO 02/30401) in view of Uhland et al. (US Patent No. 7,455,667) and further in view of Yachia et al. (US Patent No. 6,293,923). Microchips discloses the device substantially as claimed including a method for releasing one or more substances into a body cavity containing an electrolytic fluid of an individual, the system comprising: loading the one or more substances into the vesicles of a medical device (Fig. 2) for controlled release of one or more substances (abstract) into a body cavity as well as inserting the device into the body cavity (page 7, lines 1-5 disclose that the device may be implanted in a patient in a electrically conducting fluid such as urine which would be found in a body cavity) containing an electrolytic fluid (page 6, last line through page 7, line 5 discloses that the device is implanted/inserted into electroconductive/electrolytic fluid of a patient, and one of those bodily fluids is urine) comprising: a power supply having first and second terminals (Fig. 2); a plurality of blister-like vesicles mounted on a first surface (Fig. 2, 62 and 60 are labeled to identify both the electrodes and the caps, therefore as they are shown to protrude from the surface, of the microchip device 52 (which as seen in Fig. 2 discloses that 58 lies on top of the surface of the microchip device and cap 60 lies on top of 58 and together, these

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form a protrusion which can be considered a "blister-like" vesicle) they can be considered "blister-like" vesicles) mounted on a first surface, each vesicle having at least a metallic portion formed from a first metal (page 5, line 24 through page 6, line 30 discloses that each of the blister-like vesicles are electrodes and both can be made from metal); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection allowing the metallic portion to function as an anode (page 7, line 29 through page 8, line 1 disclose that 60 is the anode and 62 is the cathode, also see page 5, line 24 through page 6, line 30 as well as Fig. 2); and a cathode (62) formed from a second metal attached to the second terminal of the power supply (Fig. 2); wherein the cathode is separated from the anode by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Fig. 2 discloses that there is space between 60 and 62 and that both are exposed to the electrolytic body fluid as the fluid is labeled as 30, see page 7, line 22). Microchips, however, does not disclose that each vesicle is electrically coupled to a switch. Uhland, however, discloses a similar device and further discloses that each vesicle may be connected to a transistor/switch so that each blister could be activated independently of other blisters to selectively control what is exposed/released (col. 15, lines 64 through col. 16, line 6). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Microchips with the switches, as taught by Uhland, in order to provide selective release of individual components into the body and provide further and finer control of the device.

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Microchips in view of Uhland, however, does not disclose an inflatable balloon with magnetic portion and valve, nor expanding the balloon in the body cavity or displacing the balloon within the urinary bladder to a desired location. Yachia, however, discloses an inflatable balloon (Fig. 5b, balloon is 1) with magnetic portion (Fig. 13, 3) and a self-sealing valve (Figs. 2, 3a and 3b where valve is 5) for the purpose of delivering a treating device into the bladder so that the device may release drugs to treat the bladder (col. 4, lines 46- 48). Yachia further discloses that the device after inflation of the balloon either floats or sinks in the electrolytic fluid (col. 5, lines 64-65). Yachia further discloses that the applicator is fitted at an end thereof with a gripping device for releasably gripping the device (Fig. 5b, 23). Yachia also discloses an inflating device for inflating the balloon (Fig. 4a, 7). Yachia, however, discloses expanding a balloon in a urinary bladder (Fig. 9) and displacing the balloon within the bladder to a desired location (Fig. 13). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have coupled Microchips with the delivery device as taught by Yachia, as the device of Microchips is used for treating the urine/bladder and is implanted within that space, and Yachia discloses a device which delivers a treatment device to the bladder, the device including the balloon and its magnetic and valve elements in order to provide a device which can be delivered to the treatment area and positioned properly to allow for the most effective treatment possible (abstract of Yachia).

In reference to claim 27 see Figs. 9 and 13 of Yachia.

In reference to claim 28, see page 3, lines 33-34 of Microchips.

Response to Arguments

Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772